

**Office Of The Secretary Of Defense (OSD)
Deputy Director Of Defense Research & Engineering
Deputy Under Secretary Of Defense (Science & Technology)
Small Business Technology Transfer Research (STTR)
FY 2005 Program Description**

Introduction

The Deputy Under Secretary of Defense (Science & Technology) STTR Program is sponsoring two technology themes in this solicitation: Space propulsion technology and biomedical technology.

The Army and Air Force are participating in the OSD program this year. The service laboratories act as our OSD Agent in the management and execution of the contracts with small businesses. The service laboratories, often referred to as a DoD Component acting on behalf of the OSD, invite small business firms to submit proposals under this Small Business Technology Transfer Research (STTR) Program solicitation. In order to participate in the OSD STTR Program this year, all potential proposers should register on the DoD SBIR/STTR website as soon as you can, and should follow the instruction for electronic submittal of proposals. It is required that all bidders submit their proposal cover sheet, company commercialization report and their firm's technical and cost proposal form electronically through the DoD SBIR/STTR Proposal Submission Website at <http://www.dodsbir.net/submission>. If you experience problems submitting your proposal, call the help desk (toll free) at 1-866-724-7457. You must include a Company Commercialization Report as part of each proposal you submit; however, it does not count against the proposal page limit. Please note that improper handling of this form may result in the proposal being substantially delayed. Information provided may have a direct impact on the review of the proposal. The DoD SBIR/STTR Proposal Submission Website allows your company to come in any time (prior to the proposal submission deadline) to edit your Cover Sheets, Technical and Cost Proposal and Company Commercialization Report.

We WILL NOT accept any proposals that are not submitted through the on-line submission site. The submission site does not limit the overall file size for each electronic proposal, there is only a page limit. However, file uploads may take a great deal of time depending on your file size and your internet server connection speed. If you wish to upload a very large file, it is highly recommended that you submit prior to the deadline submittal date, as the last day is heavily trafficked. You are responsible for performing a virus check on each technical proposal file to be uploaded electronically. The detection of a virus on any submission may be cause for the rejection of the proposal. We will not accept e-mail submissions.

Firms with strong research and development capabilities in science or engineering in any of the topic areas described in this section and with the ability to commercialize the results are encouraged to participate. Subject to availability of funds, the DUSD(S&T) STTR Program will support high quality research and development proposals of innovative concepts to solve the listed defense-related scientific or engineering problems, especially those concepts that also have high potential for commercialization in the private sector. Objectives of the DUSD(S&T) STTR Program include stimulating technological innovation, strengthening the role of small business in meeting DoD research and development needs, fostering and encouraging participation by minority and disadvantaged persons in technological innovation, and increasing the commercial application of DoD-supported research and development results. The guidelines presented in the solicitation incorporate and exploit the flexibility of the SBA Policy Directive to encourage proposals based on scientific and technical approaches most likely to yield results important to DoD and the private sector.

Description of the OSD STTR Three Phase Program

Phase I is to determine, insofar as possible, the scientific or technical merit and feasibility of ideas submitted under the STTR Program and will typically be one half-person year effort over a period not to exceed six months, with a dollar value up to \$100,000. We plan to fund 3 Phase I contracts, on average, and downselect to one Phase II contract per topic. This is assuming that the proposals are sufficient in quality to fund this many. Proposals should concentrate on that research and development which will significantly contribute to proving the scientific and technical feasibility of the proposed effort, the successful completion of which is a prerequisite for further DoD support in Phase II. The measure of Phase I success includes technical performance toward the topic objectives and

evaluations of the extent to which Phase II results would have the potential to yield a product or process of continuing importance to DoD and the private sector, in accordance with Section 4.3.

Subsequent Phase II awards will be made to firms on the basis of results from the Phase I effort and the scientific and technical merit of the Phase II proposal in addressing the goals and objectives described in the topic. Phase II awards will typically cover 2 to 5 person-years of effort over a period generally not to exceed 24 months (subject to negotiation). Phase II is the principal research and development effort and is expected to produce a well defined deliverable prototype or process. A more comprehensive proposal will be required for Phase II.

Under Phase III, the DoD may award non-STTR funded follow-on contracts for products or processes, which meet the component mission needs. This solicitation is designed, in part, to encourage the conversion of federally sponsored research and development innovation into private sector applications. The small business is expected to use non-federal capital to pursue private sector applications of the research and development.

This solicitation is for Phase I proposals only. Any proposal submitted under prior STTR solicitations will not be considered under this solicitation; however, offerors who were not awarded a contract in response to a particular topic under prior STTR solicitations are free to update or modify and submit the same or modified proposal if it is responsive to any of the topics listed in this section.

For Phase II, no separate solicitation will be issued and no unsolicited proposals will be accepted. Only those firms that were awarded Phase I contracts, and have successfully completed their Phase I efforts, will be invited to submit a Phase II proposal. Invitations to submit Phase II proposals will be released at or before the end of the Phase I period of performance. The decision to invite a Phase II proposal will be made based upon the success of the Phase I contract to meet the technical goals of the topic, as well as the overall merit based upon the criteria in section 4.3. DoD is not obligated to make any awards under Phase I, II, or III. DoD is not responsible for any money expended by the proposer before award of any contract. For specifics regarding the evaluation and award of Phase I or II contracts, please read the front section of this solicitation very carefully. Every Phase II proposal will be reviewed for overall merit based upon the criteria in section 4.3 of this solicitation, repeated below:

- a. The soundness, technical merit, and innovation of the proposed approach and its incremental progress toward topic or subtopic solution.
- b. The qualifications of the proposed principal/key investigators, supporting staff, and consultants. Qualifications include not only the ability to perform the research and development but also the ability to commercialize the results.
- c. The potential for commercial (defense and private sector) application and the benefits expected to accrue from this commercialization.

In addition, the OSD STTR Program has a *Phase II Plus* Program, which provides matching STTR funds to expand an existing Phase II that attracts investment funds from a DoD acquisition program or Private sector investments. ***Phase II Plus*** allows for an existing Phase II OSD STTR effort to be extended for up to one year to perform additional research and development. ***Phase II Plus*** matching funds will be provided on a one-for-one basis up to a maximum \$250,000 of STTR funds. All ***Phase II Plus*** awards are subject to acceptance, review, and selection of candidate projects, are subject to availability of funding, and successful negotiation and award of a ***Phase II Plus*** contract modification.

The Fast Track provisions in section 4.0 of this solicitation apply as follows. Under the Fast Track policy, STTR projects that attract matching cash from an outside investor for their Phase II effort have an opportunity to receive interim funding between Phases I and II, to be evaluated for Phase II under an expedited process, and to be selected for Phase II award provided they meet or exceed the technical thresholds and have met their Phase I technical goals, as discussed Section 4.5. Under the Fast Track Program, a company submits a Fast Track application, including statement of work and cost estimate, within 120 to 180 days of the award of a Phase I contract (see the Fast Track Application Form on www.dodsbir.net/submission). Also submitted at this time is a commitment of third party funding for Phase II. Subsequently, the company must submit its Phase I Final Report and its Phase II proposal no later than 210 days after the effective date of Phase I, and must certify, within 45 days of being selected for Phase II award, that all matching funds have been transferred to the company. For projects that qualify for the Fast Track (as discussed in Section 4.5), DoD will evaluate the Phase II proposals in an expedited

manner in accordance with the above criteria, and may select these proposals for Phase II award provided: (1) they meet or exceed selection criteria (a) and (b) above and (2) the project has substantially met its Phase I technical goals (and assuming budgetary and other programmatic factors are met, as discussed in Section 4.1). Fast Track proposals, having attracted matching cash from an outside investor, presumptively meet criterion (c). However, selection and award of a Fast Track proposal is not mandated and DoD retains the discretion not to select or fund any Fast Track proposal.

Follow-On Funding

In addition to supporting scientific and engineering research and development, another important goal of the program is conversion of DoD-supported research and development into commercial products. Proposers are encouraged to obtain a contingent commitment for private follow-on funding prior to Phase II where it is felt that the research and development has commercial potential in the private sector. Proposers who feel that their research and development have the potential to meet private sector market needs, in addition to meeting DoD objectives, are encouraged to obtain non-federal follow-on funding for Phase III to pursue private sector development. The commitment should be obtained during the course of Phase I performance. This commitment may be contingent upon the DoD supported development meeting some specific technical objectives in Phase II which if met, would justify non-federal funding to pursue further development for commercial purposes in Phase III. The recipient will be permitted to obtain commercial rights to any invention made in either Phase I or Phase II, subject to the patent policies stated elsewhere in this solicitation.

Contact with DoD

General informational questions pertaining to proposal instructions contained in this solicitation should be directed to the topic authors and point of contact identified in the topic description section. Proposals should be electronically submitted. Oral communications with DoD personnel regarding the technical content of this solicitation during the pre-solicitation phase are allowed, however, proposal evaluation is conducted only on the written submittal. Oral communications during the pre-solicitation period should be considered informal, and will not be factored into the selection for award of contracts. Oral communications subsequent to the pre-solicitation period, during the Phase I proposal preparation periods are prohibited for reasons of competitive fairness. Refer to the front section of the solicitation for the exact dates.

Proposal Submission

Proposals shall be submitted in response to a specific topic identified in the following topic description sections. The topics listed are the only topics for which proposals will be accepted. Scientific and technical information assistance may be requested by using the SBIR/STTR Interactive Technical Information System (SITIS).

It is required that all bidders submit their proposal cover sheet, company commercialization report and their firm's technical and cost proposal form electronically through the DoD SBIR/STTR Proposal Submission Website at <http://www.dodsbir.net/submission>. If you experience problems submitting your proposal, call the help desk (toll free) at 866-724-7457. You must include a Company Commercialization Report as part of each proposal you submit; however, it does not count against the proposal page limit. Please note that improper handling of this form may result in the proposal being substantially delayed. Information provided may have a direct impact on the review of the proposal. The proposal submission website allows your company to come in any time (prior to the proposal submission deadline) to edit your Cover Sheets, Technical and Cost Proposal and Company Commercialization Report. We **WILL NOT** accept any proposals which are not submitted through the on-line submission site. The submission site does not limit the overall file size for each electronic proposal, only the number of pages are limited. However, file uploads may take a great deal of time depending on your file size and your internet server connection speed. You are responsible for performing a virus check on each technical proposal file to be uploaded electronically. The detection of a virus on any submission may be cause for the rejection of the proposal. We will not accept e-mail submissions.

The following is a summary of the technology areas, which are followed by the topics.

Space Propulsion Technology Area

The DoD requires higher performing solid propellants for use on space access and strategic and tactical missile systems. An extremely challenging goal is to simultaneously attain higher energy and density while maintaining acceptable physical properties. Focused efforts are needed to identify, synthesize and characterize new ingredients (fuel, oxidizer, plasticizer, binder and/or burn rate modifier) to increase energy and density of formulated solid propellant mixtures while meeting required attributes.

A second challenge of interest is the ability to achieve and maintain combustion in high speed flows for hypersonic flight. To this end we are interested in developing a hydrocarbon chemical kinetics modeling approach and capability suitable for scramjet propulsion for hypersonic flight.

We have chosen the following topics in the space propulsion technology area:

OSD05-T001	New Energetic Solid Propellant Ingredients
OSD05-T002	Chemical Kinetics Modeling Tools for Hydrocarbon Scramjet Propulsion System Design

Biomedical Technology Area

The Department of Defense is aggressively pursuing unified Force Health Protection strategies to protect Service members and their family members from health hazards associated with military service. Toward that end, DoD is undertaking strategies that promote healthy units and communities while improving both force morale and war fighting capabilities.

Ensuring the health of the force encompasses several key capabilities:

- To provide FDA-approved prevention, diagnosis and treatment items for disease and injury;
- To mobilize, deploy and sustain field medical services and support for any operation requiring military services;
- To maintain and project the continuum of healthcare resources required to provide for the health of the force;
- To operate in conjunction with beneficiary healthcare; and
- To develop training systems which provide realistic rehearsal of emergency medical and surgical procedures and unit-level medical operations.

These capabilities comprise an integrated and focused approach to protect and sustain DoD's most important resource—its Service members and their families—throughout the entire length of service commitment. Three broad capability areas of particular interest are tools and techniques for risk communication, for epidemiology research, and for delivery of health education and training unique to DoD functions.

We have chosen the following topics in the biomedical technology area:

OSD05-T003	High-Throughput Brain Injury Proteomic Microassay
OSD05-T004	Intracranial Hematoma/Burr Hole and Trauma Flap Simulator
OSD05-T005	Military Specific Advancements in Prosthetic Limb Design and Performance

All of the topic descriptions are provided on the following pages.

OSD STTR 2005 Topic Index

OSD05-T001	New Energetic Solid Propellant Ingredients
OSD05-T002	Chemical Kinetics Modeling Tools for Hydrocarbon Scramjet Propulsion System Design
OSD05-T003	High-Throughput Brain Injury Proteomic Microassay
OSD05-T004	Intracranial Hematoma/ Burr Hole and Trauma Flap Simulator
OSD05-T005	Military Specific Advancements in Prosthetic Limb Design and Performance

OSD STTR 2005 Topic Descriptions

OSD05-T001 TITLE: New Energetic Solid Propellant Ingredients

TECHNOLOGY AREAS: Materials/Processes, Space Platforms, Weapons

The technology within this topic is restricted under the International Traffic in Arms Regulation (ITAR), which controls the export and import of defense-related material and services. Offerors must disclose any proposed use of foreign nationals, their country of origin, and what tasks each would accomplish in the statement of work in accordance with section 3.5.b.(7) of the solicitation.

OBJECTIVE: Identify and develop synthesis routes for new higher energy density solid propellant ingredients that possess acceptable physical properties for higher performing solid propellants to advance space access, strategic and tactical systems.

DESCRIPTION: The DoD requires higher performing solid propellants for use on space access and strategic and tactical missile systems, however, simultaneously attaining higher energy and density while maintaining acceptable physical properties is an extremely challenging goal. Current ingredients are incapable of imparting the desired performance and insensitivity; and few new ingredients have surfaced in the past couple decades. In order to meet and compete in this technology challenge, and to avoid technological surprise, focused efforts are needed to identify, synthesize, and characterize new ingredients (fuel, oxidizer, plasticizer, binder, and/or burn rate modifiers) to increase the energy and density of formulated solid propellant mixtures while meeting other required attributes (hazard classification, lifetime, cost, performance, etc) defined by the DoD/NASA/US Industry's Integrated High Payoff Rocket Propulsion Technology (IHPRT) Program Phase III goals and beyond.

PHASE I: Conceive and identify potential candidate compounds and screen them based on their theoretical performance and other parameters. Design research strategies and experimental approaches to synthesize and characterize the key properties of promising new ingredients. Prepare sufficient new ingredient quantities in laboratory scale to allow determination of structure and permit necessary ingredient stability and sensitivity tests to be conducted.

PHASE II: Develop and refine scale-up synthesis procedure for new characterized compounds to be evaluated in formulated propellant development. Evaluate candidate propellant formulations containing the new characterized ingredients in aging, compatibility, mechanical property, thermal stability, sensitivity and performance characteristics for solid propellant applications.

PHASE III DUAL USE APPLICATIONS: Scale up and further characterize physical properties of new ingredients and/or formulated propellants tailored for space access, strategic or tactical missile system applications. Demonstrate high energy density propellant in sub-scale motor test.

REFERENCES:

1. Advanced Energetic Materials, National Research Council of the National Academies assessment, ed. R. L. Atkins, The National Academies Press, Washington, DC, 2004, pp.5-15.
2. "Request for S&T Representatives for Directed Energy Weapon, Energetic Materials, and Cruise Missile/Cruise Missile Defense Assessments," Memorandum for Assistant Secretary of the Army (Acquisition), Logistics and Technology), Assistant Secretary of the Navy (Research, Development and Acquisition), Assistant Secretary of the Air Force (Acquisition), signed by Stephen. A. Cambone (Under Secretary of Defense for Intelligence) and Ronald. M. Sega (Director, Defense Research and Engineering), Jan. 28, 2004.

KEYWORDS: Space Access, Strategic and Tactical Missiles, High Energy Density Ingredients, HEDM, Solid Propellants, Energetic Materials, Energetic Ingredients, Energetic Binders and Plasticizers, Fuel, Oxidizer, Burn Rate Modifier, Specific Impulse, Density Impulse, Insensitive, Density, Heat of Formation, Impact Sensitivity, Shock Sensitivity, Friction Sensitivity, Thermal Stability, Chemical Compatibility, IHPRT.

TECHNOLOGY AREAS: Air Platform, Materials/Processes, Space Platforms

OBJECTIVE: Develop a hydrocarbon chemical kinetics modeling approach and capability suitable for design applications for scramjet propulsion for hypersonic flight

DESCRIPTION: One of the primary challenges facing scramjet propulsion for hypersonic flight is the ability to achieve and maintain combustion in high speed flows. In essence, the combustion reaction must be initiated and completed in an extremely limited residence time (on the order of 1 millisecond) before the fuel and gases exit the vehicle for effective scramjet engine operation. For scientists and engineers developing hypersonic aircraft, a reliable design capability is needed that will allow them to develop combustion concepts that operate effectively in this environment. At present, this capability does not exist, and scramjet technology advancement follows a more heuristic development course. With the inherent risks associated with hypersonic flight, coupled with a very limited number of flight test opportunities, an improved design approach for scramjet propulsion concepts is needed that takes advantage of accurate modeling and simulation tools, especially in the area of hydrocarbon chemical kinetics, to reduce risks and add value to each flight demonstration. Much of the current knowledge in hydrocarbon chemical kinetics breaks down in the supersonic regime, where high temperatures and low densities extend into ranges where data and experience are limited. Furthermore, engine conditions associated with hypersonic flight and supersonic combustion are complicated by the fact that chemical reaction timescales are comparable to transport timescales so that the usual assumptions applicable to subsonic combustion do not apply. Improved detailed reaction models are needed for hydrocarbon fuels, particularly heavy hydrocarbons (e.g. JP fuels). Moreover, new chemical kinetics modeling tools must be flexible and computationally inexpensive, allowing a scientist or engineer to effectively explore a wide range of combustion concepts at a reasonable cost and in a reasonable amount of time. Thus, methods for reducing the detailed models to a form usable as a design tool, while maintaining the desired characteristics (heat release, ignition delay, extinction, etc.), also need to be developed. This goal requires innovation not only in the development of improved understanding of chemical kinetic phenomena, but also in structuring numerical simulation tools to optimally provide accuracy and efficiency. Finally, new modeling and simulation tools must be grounded in available data, from earlier tests or from well-planned experiments designed to demonstrate the physical event being modeled.

PHASE I: Identify key physical and chemical phenomena associated with hydrocarbon combustion and develop a modeling approach that captures important behavior in the supersonic combustion regime. Develop a structure for a chemical kinetics modeling tool suitable for scramjet propulsion system design using current state-of-the-art 3-D Navier-Stokes solvers.

PHASE II: Develop an integrated modeling tool suitable for scramjet propulsion system design, allowing parameterization of key variables identified in Phase I over a suitable design space. As a minimum, the modeling tool should be able to accommodate 16 combustion species. The code structure should be fully compatible and amenable for use with current state-of-the-art 3-D Navier-Stokes solvers. Perform numerical studies to simulate available data sets and compare the model results to these data, identifying any inherent limitations in the modeling approach. Design and execute small-scale experiments to demonstrate key aspects of the modeling tool for which data are not available. Demonstrate the efficiency of the modeling tool and the range of capability through a hypothetical design study.

PHASE III DUAL USE APPLICATIONS: It is expected that the offeror will actively pursue opportunities to apply the new design tool to develop scramjet propulsion systems for hypersonic air vehicles. This will lead to improved standoff missile capabilities for rapid response by reducing design time, cost, and risk. In addition, it will eventually contribute to global strike capability in manned systems. Commercial benefits include reduced time, risk, and cost for developing hypersonic propulsion capability for commercial space flight.

REFERENCES:

1. Mathur, T., Gruber, M., Jackson, K., Donbar, J., Donaldson, W., Jackson, T., and Billig, F., "Supersonic Combustion Experiments with a Cavity-Based Fuel Injector," Journal of Propulsion and Power, Vol. 17, No. 6, 2001, pp. 1305-1312.

2. Bates, S. C., "Assessment of Solid Hydrogen Slurry Fueling for an Airbreathing Supersonic Combustor," Journal of Propulsion and Power, Vol. 20, No. 5, 2004, pp. 793-800.

KEYWORDS: hypersonic, scramjet, chemical kinetics, combustion, supersonic combustion, hydrocarbon fuels, ignition, extinction

OSD05-T003 **TITLE:** High-Throughput Brain Injury Proteomic Microassay

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: To develop and validate a miniature high-throughput assay capable of detecting and quantifying brain injury-specific biomarkers in relatively small volumes of whole blood (2 -200 uL) and be adaptable to interface with a hand-held personal digital assistant (PDA).

DESCRIPTION: Traumatic brain injury (TBI) has accounted for 15-25% of all combat casualties since World War II (Carey 1996). Furthermore, over 50% of all moderate-severe TBIs from Desert Storm resulted in death (Bellamy and Zajtchuk 1991). Unlike other organ-based diseases where rapid diagnosis employing biomarkers prove invaluable to guide treatment of the disease, no such rapid, definitive diagnostic tests exist for traumatic brain injury. Diagnosis of TBI and assessment of its severity currently rest in the subjective physical examination of the casualty using the Glasgow Coma Scale (GCS) or neurologic examination. Neither examination is routinely taught to the front-line medic nor are they sensitive to subtle changes in the magnitude of brain injury. Given the frequency and gravity of TBI in the combat environment a portable, objective, neurochemical assessment of brain injury severity would prove invaluable for managing brain-injured casualties. Such a test would guide the implementation of appropriate triage and management strategies from the front lines to the intensive care unit (ICU).

To address this need, research efforts are currently underway to identify and validate blood-borne biomarkers specific to the severity, mechanism, and cellular pathology of injury (Pike 2001; Wang 1998; Newcomb 1997; Pike 2004). To this end, very significant progress has been to date. Practical application of this technology to the combat arena, however, necessitates miniaturization of standard biochemical assays.

Current trends in casualty information management indicate that medical information flow on the battlefield will soon become digital. As such, the final biomarker assay system will ultimately need to be adapted for use with a hand-held PDA-like device such as the Battlefield Medical Information System-Tactical (BMIS-T).

In light of the above needs, the commercial development of a novel, portable, high-throughput, microassay system is being sought. This platform should be lightweight, sensitive, specific, and adaptable. Specifically, the system should be flexible enough to incorporate additional newly discovered biomarkers and be readily compatible with currently available PDA technology.

PHASE I: The goal of this phase is to establish the feasibility of developing a miniature biomarker assay. The assay can be ELISA (enzyme linked immunosorbant assay)-based, utilize novel methods such as aptamers and phage-displayed single chain antibody fragments, or any other reliable means for detecting and quantifying biomarkers in small (2-200 uL) samples of human serum (Loomans 2003; Lochner 2003; Zeravik 2003; Zhi 2003). Proof-of-concept will include assessments of reproducibility, sensitivity, and specificity as compared to standard larger-scale laboratory tests.

PHASE II: The assay in Phase I will be used to develop a PDA-compatible device capable of communicating data from multiple biomarker assays to the hand-held. The final device should be lightweight and able to withstand the military operational environment without degradation in function. Durability will be assessed as ability to withstand impact, operate in a wide range of ambient temperatures (arctic to desert environments), and amount of power required to operate the device.

PHASE III DUAL USE APPLICATIONS: Miniaturized biomarker assays have widespread applications in both the military and civilian sectors. This assay could be adapted to detect biomarkers specific to a variety of organ-based diseases (cardiac, hepatic, renal). The portability of this system will allow for rapid, early diagnosis of disease states

while the patient is still en route to the hospital. Furthermore, this technology permits bedside monitoring of changes in biomarker levels in a manner similar to bedside measurements of arterial blood gases and electrolytes (e.g. I-Stat).

REFERENCES:

1. Bellamy R, Zajtcuk R. (1991) The Management of Ballistic Wounds of Soft Tissue. In: Textbook of Military Medicine (Zajtcuk R, ed), Washington, D.C.: Office of the Surgeon General, pp 163-220
2. Carey ME. (1996) Analysis of wounds incurred by U.S. Army Seventh Corps personnel treated in Corps hospitals during Operation Desert Storm, February 20 to March 10, 1991. J Trauma 40:S165-169.
3. Lochner N, Lobmaier C, Wirth M, Leitner A, Pittner F, Gabor F. Silver nanoparticle enhanced immunoassays: one step real time kinetic assay for insulin in serum. Eur J Pharm Biopharm. 2003 Nov;56(3):469-77.
4. Loomans EE, van Doornmalen AM, Wat JW, Zaman GJ. High-throughput screening with immobilized metal ion affinity-based fluorescence polarization detection, a homogeneous assay for protein kinases. Assay Drug Dev Technol. 2003 Jun;1(3):445-53.
5. Pike BR, F.J., Dutta S, Johnson E, Wang KKW, Hayes RL, Accumulation of non-erythroid aII-spectrin and calpain-cleaved aII-spectrin breakdown products in cerebrospinal fluid after traumatic brain injury in rats. J of Neurochemistry, 2001. 78: p. 1297-1306.
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7. Newcomb, et al., Immunohistochemical study of calpain-mediated breakdown products in alpha-spectrin following controlled cortical impact injury in the rat. J Neurotrauma, 1997. 14: p. 369-383.
8. Wang KKW, P.R., Nath R, McGinnis KM, Whitton M, Talanian RV, Glantz SB and Morrow JS, Simultaneous degradation of aII and bII spectrin by caspase-3 (CPP32) in apoptotic cells. J. Biol Chem, 1998. 273: p. 22490-22497.
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KEYWORDS: proteomics, biomarkers, assay, ELISA, traumatic brain injury, nanotechnology, microarray

OSD05-T004 TITLE: Intracranial Hematoma/ Burr Hole and Trauma Flap Simulator

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: To prepare a proof-of-concept, design, develop, build and demonstrate a simulation training system that will deliver didactic training in, and allow simulated performance of emergent operative management of traumatic intracranial hematomas. This simulator will be utilized in the training of military and civilian health care professionals, (i.e., surgeons, special forces medics, as well as allied, non-governmental organization and foreign national healthcare professionals).

DESCRIPTION: This topic falls into a category of “virtual workbench”, “part-task” simulators. (Though part-task mannequin-based simulators will be considered, the preference is for the smallest/lightest form factor technically possible. It is believed that the technology exists to allow this device to be developed as a virtual workbench.) In a “part-task” simulation, rather than simulate an entire mission or procedure from start to finish, certain part(s) of a

mission / procedure are simulated, e.g., those that are most difficult, most dangerous, least-encountered, highest-risk, etc. The system should promote the acquisition and maintenance of skills in this and related surgical techniques and provide a level of training not possible using the traditional surgical training methods currently in use. Traumatic hematomas are a military-relevant, manageable form of secondary injury to the brain. Their presence can cause direct injury to brain tissue resulting in edema, and can cause increased intracranial pressure that can be followed by brain shift, herniation, and ischemic brain injury. Intracranial hematomas are usually classified as epidural, subdural or intracerebral. In military medicine, traumatic hematomas can be diagnosed in far-forward echelons of care/austere environments where a neurosurgeon is not available. In these cases, emergent treatment must still be rendered in order to allow the patient to be stabilized for transport to definitive neurosurgical care. This management includes the creation of burr holes in the skull to allow diagnosis (exploratory burr holes) and evacuation of hematoma for reduction and monitoring of intracranial pressure. In some cases a flap of bone must be removed in rapid succession to allow immediate control of bleeding and to relieve the effects of brain swelling. These procedures can be performed with manual twist drills and Gigli saws (this would be encountered in austere or combat medical environments), or with electric or pneumatic drills and saws.

The following performance objectives should be met: 1. Simulator should provide visual and tactile feedback consistent with the visualization and manipulation of the skull. For virtual workbench: 2. Techniques for simulation of physiological events (edema, hemorrhage, cerebrospinal fluid leak, etc) should be explored. For Virtual Workbench: 3. Integrate realistic modeling of local tissue surface deformation. 4. Realistic lighting simulation should be explored to simulate moist/bleeding tissue surfaces and resulting lighting effects. 5. Real-time collision processing should be explored to detect local collisions between instruments as well as between instruments and tissues. 6. Integrate a computer-based geometric model of the skull that can display the different characteristics of adult and pediatric anatomy. 7. Integrate the physics processing, device tracking, multimedia, and graphics rendering that will be applicable to all complex real-time environments. For both mannequin and virtual workbench solutions: 8. Allow for utilization of synthesized imaging modalities that would be available to the surgeon in a field environment. (this should be able to be adjusted to specific echelons of care, e.g. no imaging; x-ray and ultrasound only; or addition of fluoroscopy and CT to resemble a general hospital or hospital ship.) Include 3-D transparent views for demonstrating real-time position of instruments, tissues and hematomas. 9. Of particular interest are technologies and techniques that present the user with multiple patient conditions and complications that might be encountered during management. 10. Of particular interest are technologies and techniques that allow the user to manage the condition presented by the simulation. Management should be based on clinical protocols developed and accepted by credentialed neurosurgeons. 11. Cases and management should be based on embedded metrics for performance assessment and training. 12. User interface should contain a module that allows the teaching, rehearsal, testing and results tracking of the user. 13. Didactic content should include a SCORM-compliant browser-based didactic curriculum that can run separately or in series with the simulator. Content should encompassing peri-procedural aspects of emergent management, including patient preparation, local or general anesthesia, indications and contraindications, complications, and patient transport. 14. Simulation interoperability should be addressed such that the simulator can be integrated with existing and planned DoD training systems.

PHASE I: Phase I will develop a feasibility concept and plan for developing and /or applying various innovative simulation technologies to the management of intracranial hemorrhage. Performance objectives listed in topic description should be addressed.

PHASE II: Phase II will develop and demonstrate a working functional prototype of the surgical procedure simulator. The interface platform will enable the integration of individual patient cases and therapeutic treatment. The simulation should include epidural and subdural hematoma management in adults and children to include presenting an array of complications.

PHASE III DUAL-USE COMMERCIALIZATION: The focus will be on commercializing a burr hole/trauma flap training system that is fieldable in both the military and civilian arenas. The training can be expanded for other military and civilian relevant craniofacial injuries as well as for rehearsing various craniotomy approaches. In the future the system should be capable of allowing surgeons to train for patient-specific cases (e.g. utilizing imaging data from actual patients).

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KEYWORDS: surgical simulation; epidural hemorrhage; subdural hematoma; neurotrauma; neurosurgery; field surgery; combat casualty care; training; simulation; craniotomy; trauma; military medicine; surgical skills training

OSD05-T005 **TITLE:** Military Specific Advancements in Prosthetic Limb Design and Performance

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Design prosthetic limbs and componentry to allow improved performance in military specific activities of daily living in one of eight areas 1.) Materials and design to improve durability, 2.) Enhancement of power sources to provide extended periods of high-energy without increased load, 3.) Designs to enable multi-axial joint movements, 4.) Designs to enable comfort and proper fit, 5.) Advancements in hand design/technology to provide additional prehension options such as spherical or lateral grasp. 6.) Designs to decrease energy cost during military specific tasks. 7.) Advancements in Socket design and lining, and 8.) Advancements in microprocessor-controlled joint motion.

DESCRIPTION: Advancements in technology should allow increased utilization of prosthetic componentry for advanced skills specific to military activities, which include improvements in comfort, and stability during challenging environments incorporating high load or activity in altered terrain and temperatures, Therefore, this topic addresses the need for upper and lower extremity prosthetic limb performance and maintenance to support soldiers deciding to remain active duty.

A large number of injured soldiers recover to high functional levels with hopes of remaining active duty in service to their country. However their recovery remains limited by available prosthetic technology. Basic soldiers' skills include many bilateral upper extremity tasks such as donning/doffing military gear, manipulating computerized control panels and engaging various forms of weaponry. Tasks demands for the lower extremities include loaded marches for long distances over uneven terrain in various climates, climbing, running and rucksack maneuvers.

Specific areas of interest include:

1. Demand for more versatile, higher performance prosthetics with more lifelike external coverings for gloves and feet. According to Childress, very little technical progress has occurred in this area upper extremity terminal ends. "..... Gloves of the future must be better than current ones. They must be attractive, tough, stain resistant and affordable". [4]
2. Batteries, such as the typical nickel-cadmium cells, are a very common maintenance problem for prosthetic users. High prosthesis use hastens battery failure and few technological improvements have occurred in the past 20 years. The development of a new higher-power battery needs to also address load factors as different from the high energy batteries used for computers, telephones etc.
3. Newer technologies for wrist motion should provide movements in more directions for both above and below elbow amputee levels along with possible control schemes to perform coordinated function with less need for visual attention.

4. Advancements are needed in the durability of harnessing and cabling systems along with new control mechanisms to meet high task demands of varied temperature and moisture environments.
5. Dynamic feet are needed with light-weight, multi-axial, foot-ankle coordinated componentry to increase stability on uneven outdoor terrain.
6. Improvements are needed for hand designs to provide independent digit movement or a conformable grip in which the fingers adapt and automatically take shape of the object. (additional grasp options such as spherical or lateral grip)
7. New designs for socket liners should provide adequate control of moisture and pressure using a thin, compliant barrier between the amputee's skin and the more rigid, weight bearing portions of the prosthetic socket.
8. Further advancements in microprocessor-controlled prosthetic components for finely tuned movement efficiency during walking/running and navigation of various terrains to include slopes and steps.

PHASE I. Develop a concept and design a prosthetic component that can be used by military persons with upper or lower extremity limb loss. Conduct an engineering pass to incorporate identified necessary changes into the design followed by fabrication of manufacturing precursor devices for testing. Coordinate with applicable government and civilian health care organizations and facilities to access what would be required to execute Phase II.

PHASE II. Design and develop a prototype of the tool and test the prosthetic componentry within a suitable civilian/military clinical population. Demonstrate the prosthetic componentry as part of a performance study for military/civilian activities.

PHASE III. Extend the prosthetic componentry to multiple DOD, VA and civilian health care systems and incorporate local/regional user response grid preparation and training for executing integrated military/civilian medical responses to use of componentry in vocational and avocational pursuits for patient with traumatic limb loss.

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KEYWORDS: military tasks, amputee, prosthesis, hand, socket liners, multiaxial joint, microprocessor-controlled, upper extremity, lower extremity, energy cost, gloves, cable systems, battery power, harness systems